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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,816	03/26/2004	Shyr-Jiann Li	CL001507	8621

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EXAMINER	
MOORE, WILLIAM W	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,816	LI ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 2 and 19, drawn to an isolated polypeptide having an amino acid sequence at least 99% identical to the amino acid sequence of SEQ ID NO:2, classified in class 435, subclass 226.

II. Claims 3 and 20, drawn to an isolated antibody capable of specifically binding to a polypeptide having an amino acid sequence at least 99% identical to the amino acid sequence of SEQ ID NO:2, classified in class 530, subclass 387.1.

III. Claims 4-6 and 8-10, drawn to an isolated polynucleotide encoding a polypeptide having an amino acid sequence at least 99% identical to the amino acid sequence of SEQ ID NO:2, to nucleic acid arrays, vectors and host cells comprising same, and to recombinant method of making the encoded product utilizing said host cells, classified, *inter alia*, in class 536, subclass 23.2.

IV. Claim 7, drawn to a non-human transgenic animal comprising a polynucleotide encoding a polypeptide having an amino acid sequence at least 99% identical to the amino acid sequence of SEQ ID NO:2, classified in class 800, subclass 8.

V. Claim 11, drawn to a method for detecting a polypeptide having an amino acid sequence at least 99% identical to the amino acid sequence of SEQ ID NO:2 by contacting it with an undesignated agent, classified in class 435, subclass 7.4.

VI. Claim 12, drawn to a method for detecting a polynucleotide encoding a polypeptide having an amino acid sequence at least 99% identical to the amino acid sequence of SEQ ID NO:2 by hybridization with an oligonucleotide probe, classified in class 536, subclass 6.

VII. Claim 13, drawn in part to a method for identifying a modulator capable of altering the function of polypeptide having an amino acid sequence at least 99% identical to the amino acid sequence of SEQ ID NO:2, classified in class 435, subclass 7.72.

VIII. Claim 13 drawn in part to, and claim 14 drawn specifically to, a method for identifying a modulator of the expression of a polynucleotide encoding a polypeptide having an amino acid sequence at least 99% identical to the amino acid sequence of SEQ ID NO:2, classified in class 435, subclass 4.

IX. Claim 15, drawn to a method of detecting an agent capable of forming a complex with a polypeptide having an amino acid sequence at least 99% identical to the amino acid sequence of SEQ ID NO:2, classified in class 435, subclass 7.1.

X. Claims 16-18, drawn to a composition comprising an unspecified agent and methods of use thereof in treating a disease or condition mediated by a polypeptide having an amino acid sequence at least 99% identical to the amino acid sequence of SEQ ID NO:2, classified in class 514, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects.

Inventions of Groups I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as solid phase chemical synthesis.

Inventions of Groups I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects.

Inventions of Groups I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the method of Group V does not require the use of a product of Group I but instead requires the use of an undesignated agent, and they have different modes of operation, different functions, and different effects.

Inventions of Groups I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the method of Group VI does not require the use of a product of Group I but instead requires the use of an oligonucleotide probe, and they have different modes of operation, different functions, and different effects.

Inventions of Groups I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as the *in vitro* removal of the invariant chain from MHC class II molecules according to page 3 of the specification.

Inventions of Groups I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as the removal of the invariant chain (Ii) from MHC class II molecules according to page 3 of the specification.

Inventions of Groups I and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as the removal of the invariant chain (Ii) from MHC class II molecules according to page 3 of the specification.

Inventions of Groups I and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the compositions of Group X may not comprise the product of Group I and methods of Group X cannot use the product of Group I but instead require the use of an undesignated product, and they have different modes of operation, different functions, and different effects.

The invention of Group II is unrelated to the inventions of Groups III through X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the antibody of Group II is not disclosed to be comprised within products and compositions of Groups III, IV and X and is not disclosed as capable of use together with methods of Groups V through IX and the different inventions have different modes of operation, different functions, and different effects.

The invention of Group III is unrelated to the inventions of Groups IV and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the polynucleotide of Group III is a chemical entity structurally different than the products of Groups IV and X and requires a separate search in the patent and non-patent literature and the different inventions have different modes of operation, different functions, and different effects.

The invention of Group III is unrelated to the inventions of Groups V through VII and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the polynucleotide of Group III is not disclosed as capable of use together with methods of Groups V through VII and IX and the different inventions have different modes of operation, different functions, and different effects.

Inventions of Groups III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group II as claimed can be used in a materially different process of using that product such as the recombinant production of the encoded product.

The invention of Group IV is unrelated to the inventions of Groups V through X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the transgenic animal of Group III is not disclosed as capable of use together with methods of Groups VI through X, nor can it be comprised within a composition of Group X, and the different inventions have different modes of operation, different functions, and different effects.

The invention of Group V is unrelated to the inventions of Groups VI through IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the method of Group V is not disclosed as capable of use together with the methods of Groups VI through IX, and the different inventions have different modes of operation and different functions.

Inventions of Groups V and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the method of Group V is not disclosed as capable of use together with a method requiring the undesignated product of Group X, nor disclosed to be comprised by a composition of Group X, and the different inventions have different modes of operation, different functions, and different effects.

The invention of Group VI is unrelated to the inventions of Groups VII through IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the method of Group VI is not disclosed as capable of use together with methods of Groups VII through IX, and the different inventions have different modes of operation and different functions.

Inventions of Groups VI and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the different inventions are not disclosed as capable of use together where the oligonucleotide required by the method of Group VI is not disclosed as capable of use together with a method requiring the undesignated product of Group X, nor disclosed to be comprised by a composition of Group X, and the different inventions have different modes of operation, different functions, and different effects.

The invention of Group VII is unrelated to the inventions of Groups VIII and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the method of Group VII is not disclosed as capable of use together with the methods of Groups VIII and IX, and the different inventions have different modes of operation and different functions.

Inventions of Groups VII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the polypeptide required by the method of Group VII is not disclosed as capable of use together with a method requiring the undesignated product of Group X, nor disclosed to be comprised by a composition of Group X, and the different inventions have different modes of operation, different functions, and different effects.

Inventions of Group VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the method of Group VIII is not disclosed as capable of use together with the method of Group IX, and the different inventions have different modes of operation and different functions.

Inventions of Groups VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the cell required by the method of Group VII is not disclosed as capable of use together with a method requiring the undesignated product of Group X, nor

disclosed to be comprised by a composition of Group X, and the different inventions have different modes of operation, different functions, and different effects.

Inventions of Groups IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together where the polypeptide required by the method of Group IX is not disclosed as capable of use together with a method requiring the undesignated product of Group X, nor disclosed to be comprised by a composition of Group X, and the different inventions have different modes of operation, different functions, and different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Justin D. Karjala on 7 September 2005 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Requirements for Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be

allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
7 September 2005

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER